UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,929	06/29/2001	Ki-Seung Choi	EF321688773U	9906

21003 7590 12/09/2002

BAKER & BOTTS
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER
CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/831,929	Applicant(s) CHOI ET AL.	
	Examin r Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on th cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of request for extension of time, declaration under 37 CFR 1.132 and amendment A, all dated 9-26-02 is acknowledged.

Claims 1 has been canceled and a new claim 6 has been added. Claims 2-6 are pending prosecution.

The following rejection has been maintained for reasons of record:

Claim Rejections - 35 USC § 103

1. Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 5,278,178 to Hsu and SU 1687261 A1 (hereafter SU '261).

Instant claims are directed to a biocide composition comprising 3-isothiazolone and polyhexamethylene guanidine phosphate and a method of killing or restraining the growth of bacteria.

Hsu teaches synergistic microbicidal and biocidal combination compositions comprising 3-isothiazolone mixtures made up of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one and one or more of other antimicrobial compounds. Hsu teaches that the compositions are useful as commercial biocides for effective and broader control of microorganisms (abstract, col. 2, lines 3-54). Instant specification describes the same compounds taught by Hsu as more preferable isothiazolone compounds (page 6, lines 1-2). Hsu teaches the ratios of isothiazolones as 3:1 (col. 2, lines 56-60), which is within the claimed ratio of 1:20 to 20:1. The other antimicrobial compounds of Hsu are listed in col. 3, lines 1-10. Hsu also teaches additives such as solvents, dispersion agents, surfactants (col.3, lines 30-32), which read on the instant additives for emulsion products (instant claim 4).

Hsu does not teach the instant combination of isothiazolone and polyhexamethylene guanidine phosphate. However, Hsu suggests that a combination of two isothiazolones and other antimicrobial compounds results in a synergy, which affords a more effective and broader control of microorganisms (col. 2, lines 6-15).

SU '261 teaches polyhexamethylene guanidine gluconate as an active component in disinfecting compositions, useful for improving the disinfecting properties of the composition (abstract). SU '261 does not teach isothiazolone compounds of the instant invention. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine polyhexamethylene guanidine gluconate of SU '261 with the isothiazolone compounds of Hsu because both the references teach compositions containing antimicrobial compounds for disinfecting or preventing microbial contamination. Therefore, one of an ordinary skill in the art would have expected to achieve a synergistic effect in controlling or preventing microbial growth by combining the two disinfectants.

SU '261 does not teach polyhexamethylene guanidine phosphate and instead teaches gluconate salt of the compound. However, absent any criticality, one of an ordinary skill in the art at the time of the instant invention would have expected the same antimicrobial effect with any salt of polyhexamethylene guanidine i.e., a hydrochloride or gluconate or phosphate salt. With respect to the claimed ratio of isothiazolone and polyhexamethylene guanidine salt, it would have been obvious for one of an ordinary skill in the art to optimize the ratios of different antimicrobial agents in composition containing combination of antimicrobials, such that maximum antimicrobial effect is achieved.

2. Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 5,278,178 to Hsu and SU 1687261 A1 (hereafter SU '261), and further in view of JP 10175809(hereafter JP '809, submitted on PTO-1449).

The teachings of Hsu and SU '261 have been discussed above. Neither teaches a combination of isothiazolone and polyhexamethylene guanidine phosphate. However, Hsu suggests that a combination of isothiazolones and other antimicrobials result in a synergistic effect and provide broader control over microorganisms.

JP '809 teaches industrial antimicrobial compositions comprising isothiazolones and polyhexamethylene guanidine hydrochloride and suggests that the synergistic composition is effective against bacteria, fungi, yeast, algae and actinomycetes.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine isothiazolones of Hsu and polyhexamethylene guanidine gluconate of SU '261, with an expectation to achieve a synergistic effect in preventing and controlling microbial growth. Further, optimizing the amounts of individual antimicrobial agents in a composition so as to achieve a maximum antimicrobial effect would have been obvious for one of an ordinary skill in the art.

Although JP '809 teaches hydrochloride salt of polyhexamethylene biguanidine and not a phosphate salt, as explained above, absent any criticality one of an ordinary skill in the art at the time of the instant invention would have expected the same antimicrobial effect with any salt of polyhexamethylene guanidine i.e., a hydrochloride or gluconate or phosphate salt.

Claim 1 has been canceled and new claim 6 has been added in place of claims 1. Accordingly, the above rejections are applied to claim 6.

Response to Arguments

Applicant's arguments and declaration under 37 CFR 1.132, filed 9-26-02 have been fully considered but they are not persuasive.

Instant claims 2-4 and 6 are directed to a composition and claim 5 is directed a sterilization method, using the composition of claim 1. Applicants traverse the rejection of claims 1-5 under 35 USC 103 over a combination of Hsu and SU '261 OR Hsu and SU in view of JP because the use of a phosphate salt of polyhexamethyleneguanidine (PHMG) is critical to the instant composition as compared to the gluconate salt of prior art (SU '261). This was also stated in the declaration, along with the supporting evidence shown as the lower MIC (minimum inhibitory concentration) of the phosphate salt of the compound as opposed to the higher MIC of gluconate slat. Applicants argue that the MIC of phosphate salt of PHMG is significantly lower than MIC of gluconate salt, and that the antibiotic ability is surprisingly and unexpectedly higher. However, this argument is not persuasive because, the results presented in the declaration do not compare the efficiency of phosphate and gluconate salts of PHMG in the presence of isothiazolone. Examiner notes that the instant claims require a combination of PHMG phosphate and isothiazolone. Thus, the comparative examples of declaration are not commensurate with the scope of the claimed invention. Besides, while applicants show that the MIC of phosphate salts of PHMG are better than the gluconate salts, examiner notes that the hydrochloride salts (taught by JP) exhibited better MIC, if not equal MIC values, with several bacterial strains than the claimed phosphate salts (table B of declaration). Therefore, it is examiner's position that the efficacy of the phosphate salt of PHMG is not always "surprisingly and unexpectedly" better than other salts, such as gluconate and hydrochloride, of PHMG, as argued by applicants.

Further, the variation in the MIC values seen with the different salt forms of the same compound, PHMG, is not unexpected and one of an ordinary skill in the art would have expected such variation with different salt forms owing to their solubility and other parameters. Besides, determining the MIC values of various salt forms and choosing the salt with lower MIC values by routine experimentation, would have been within the scope of a skilled artisan.

Applicants further argue that the phosphate salts of PHMG exhibit properties such as no stimulus on skin, thermal stability, low cost of the materials, easier to handle and stability over a pH range of 4 to 10. However, applicants have not provided any comparative evidence showing the same nor the instant claims do not recite any of these properties, and accordingly the arguments are moot.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi S Channavajjala
Examiner
Art Unit 1615
December 6, 2002

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600